DURECT Corporation Announces Second Quarter 2015 Financial Results and Update of Programs

CUPERTINO, Calif., Aug. 3, 2015 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the second quarter of 2015. Total revenues were $4.4 million and net loss was $5.5 million for the three months ended June 30, 2015 as compared to total revenues of $4.6 million and net loss of $5.5 million for the three months ended June 30, 2014.

At June 30, 2015, we had cash and investments of $37.8 million, compared to cash and investments of $34.9 million at December 31, 2014. At June 30, 2015, we had $19.8 million in long term debt.

"The second quarter marked significant progress on multiple fronts," stated James E. Brown, D.V.M., President and CEO of DURECT. "We are excited to have received feedback from the FDA on the outline of the new POSIDUR™ Phase 3 clinical trial which is intended to provide the data necessary for a robust NDA resubmission. For DUR-928, we completed a positive Phase 1 multiple-ascending-dose study with our oral formulation program, are preparing to start Phase 1 studies with our injectable formulation program and today we are reporting positive data from an animal stroke model. Regarding REMOXY®, Pain Therapeutics has stated that they have substantially completed the transition of REMOXY from Pfizer and that they expect to resubmit the REMOXY NDA in the first quarter of 2016. Also, our sublicensee, Orient Pharma, has initiated their ORADUR-ADHD Phase 3 study in Taiwan."

Update of Selected Programs:

- **POSIDUR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot**. In February 2014, we received a Complete Response Letter from the FDA. Based on its review, the FDA determined that they could not approve the NDA in its present form, stating the NDA did not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA indicated that additional clinical safety studies would need to be conducted. Based on multiple interactions with the FDA, we announced in June 2015 that we plan to conduct a new POSIDUR Phase 3 clinical trial consisting of approximately 300 patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. DURECT anticipates beginning the trial in the fall of 2015 and expects that it will take approximately one year to complete enrollment. This clinical trial is designed to generate data necessary to support an NDA resubmission. POSIDUR is our investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended to deliver bupivacaine to provide up to three days of pain relief after surgery. We are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights, while at the same time we are evaluating whether to commercialize POSIDUR on our own in the U.S. in the event that we determine that is the preferred route of commercialization.
- **Epigenomic Regulator Program.** DUR-928, the Epigenomic Regulator Program's lead product candidate, is an endogenous, small molecule, new chemical entity (NCE), which may have broad applicability in several metabolic diseases such as nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH), and in acute organ injuries such as acute kidney injury. Previously we communicated that the biological activity of DUR-928 has been demonstrated in 6 different animal disease models involving three animal species. Three of these models represent acute organ injury (endotoxin shock, kidney, and liver) and three represent chronic disorders of hepatic lipid accumulation and dysfunction (e.g., NAFLD and NASH). Today we are reporting that DUR-928 provided protection against ischemic damage to the brain in a rat stroke model. In this study, a number of measures (lesion volume, edema volume and T2 lesion as determined by MRI, plus body weight recovery and behavioral recovery) were taken at 1 day and at 7 days after induction of the stroke lesion. In this study, lesion volumes and brain edema were statistically significantly reduced compared to placebo at day 1, and T2 lesions (a measure of cell viability) were statistically significantly improved at day 1 and day 7. Other measurements showed a consistent trend in favor of DUR-928 in this model. The data from this stroke model provides further support to our other acute animal models and is suggestive of DUR-928's potential use against ischemic damage and acute organ injuries. On March 2, 2015 we announced that DUR-928 had successfully completed a single dose, oral administration Phase 1 clinical

trial and on May 18, 2015 we announced the successful completion of a multiple-ascending-dose, oral administration Phase 1 clinical trial. We are currently mapping out our strategy for taking the oral version of DUR-928 into patients. In addition, we are preparing for our Phase 1 clinical studies with an injectable formulation of DUR-928 in the second half of this year.

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Based on DURECT's ORADUR® technology, REMOXY is a unique long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse. In May 2015, Pain Therapeutics stated that the transition of the program back from Pfizer was substantially complete, and that they expect to resubmit the NDA in the first quarter of 2016. The extended release oxycodone market is ~$2.4 billion in the U.S. alone, and we are eligible for a potential royalty on REMOXY between 6.0% to 11.5% of net sales depending on sales volumes.
- **Relday (Risperidone Program).** Relday is a proprietary, long-acting, once-monthly subcutaneous injectable formulation of risperidone. To provide context, an existing long-acting injectable risperidone product that achieved$1.2 billion in global net sales in 2014 requires drug reconstitution prior to use and twice-monthly, intramuscular injections. Zogenix (our licensee) has previously announced positive results from a single-dose Phase 1 clinical trial of Relday at the full dose range anticipated to be used in clinical practice. Zogenix commenced a multi-dose trial in the first quarter of 2015 and expects to have top-line data in the third quarter of 2015. Zogenix has also stated that it is targeting an end-of-Phase 2 meeting with the FDA by early 2016.
- **ORADUR-ADHD Program.** In 2013, we selected a formulation for the lead program in our ORADUR-ADHD (Attention Deficit Hyperactivity Disorder) program, ORADUR-Methylphenidate. This formulation was chosen based on its potential for rapid onset of action, long duration with once-a-day dosing and target pharmacokinetic profile as demonstrated in a Phase 1 trial. In addition, this product candidate utilizes a small capsule size relative to the leading existing long acting products on the market and incorporates our ORADUR anti-tampering technology. Orient Pharma, our licensee in defined Asian and South Pacific countries, has initiated a Phase 3 study in Taiwan and anticipates completing it in 2016. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan, and are engaged in licensing discussions with other companies.
- **Feasibility Projects and Other Activities.** During the second quarter of 2015, we continued work on several feasibility projects and have multiple discussions underway with other parties about new feasibility projects which are designed to demonstrate that our technologies can achieve the drug delivery objectives set forth by our collaborators and are worthy of further development. The Relday program and the Santen ophthalmic program are two such projects which have matured into development and license agreements.
- **Business Development Activities.** We have multiple programs that may potentially be licensed over the next 12-18 months. These include POSIDUR, DUR-928, ORADUR-ADHD (territories outside certain Asian and South Pacific markets), as well as various other programs which we have not described publicly in detail.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2015 results will be broadcast live over the internet at4:30 p.m. Eastern Time on August 3 and is available by accessing DURECT's homepage at www.www.durect.com and clicking "Investor Relations." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

About DURECT Corporation

DURECT is a biopharmaceutical company with expertise in drug discovery, drug delivery and drug development, applying those skills primarily to therapeutics in the fields of pain management, CNS disorders, acute organ injury and metabolic diseases. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as improved abuse deterrence, convenience, adherence, efficacy and safety for small molecule and biologic drugs. Late stage development programs of this nature include POSIDUR and REMOXY. DURECT's Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1 clinical testing. DUR-928 is an endogenous small molecule that is an epigenomic modulator of cellular activities involved in lipid homeostasis, metabolic disease, inflammation and cell survival. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding regulatory matters, including anticipated meetings and submissions for POSIDUR, REMOXY and Relday and potential FDA approval of our product candidates, anticipated clinical trials (including timing and results) for POSIDUR, DUR-928, Relday, ORADUR-Methylphenidate and our other drug candidates, potential royalties fromPain Therapeutics, the potential benefits and uses of our drug candidates, potential markets for our product candidates, the potential license of POSIDUR, DUR-928, ORADUR-ADHD and other products and other potential business development activities are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, the risk that the clinical trial of POSIDUR will take longer to conduct than anticipated or result in data that will not support a successful resubmission, development of REMOXY may be significantly delayed and adversely affected by Pfizer's discontinuation of its development, the risk that Pain Therapeutics will discontinue development of REMOXY, the risk of adverse decisions by regulatory agencies, including rejection of meeting requests, requests for additional information or product non-approval or non-acceptance of our POSIDUR, REMOXY or other NDA submissions, delays and additional costs due to requirements imposed by regulatory agencies, additional time and resources that may be required for development, testing and regulatory approval of our Epigenomic Regulatory Program, potential adverse effects arising from the testing or use of our drug candidates, the potential failure of clinical trials to meet their intended endpoints, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and risks related to our (and our third party collaborators where applicable) ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of product candidates, manufacture and commercialize product candidates, obtain marketplace acceptance of product candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q for the quarter ending March 31, 2015 filed with the Securities and Exchange Commission on May 1, 2015, under the heading "Risk Factors."

DURECT CORPORATION
CONDENSED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands, except per share amounts)
(Unaudited)

	Three months ended June 30		Six months ended June 30	
	2015	2014	2015	2014
Collaborative research and development and other revenue	$ 1,778	$ 1,735	$ 3,516	$ 5,247
Product revenue, net	2,663	2,846	5,698	5,627
Total revenues	4,441	4,581	9,214	10,874
Operating expenses:				
Cost of product revenues	1,022	1,091	2,028	2,154
Research and development	5,638	6,088	11,005	11,557
Selling, general and administrative	2,724	2,850	5,544	6,213
Total operating expenses	9,384	10,029	18,577	19,924
Income (loss) from operations	(4,943)	(5,448)	(9,363)	(9,050)
Other income (expense):				
Interest and other income (expenses)	23	3	151	6
Interest expense	(558)	(33)	(1,119)	(34)
Net other income (expense)	(535)	(30)	(968)	(28)
Net loss	$ (5,478)	$ (5,478)	$ (10,331)	$ (9,078)
Net loss per share				
Basic	$ (0.05)	$ (0.05)	$ (0.09)	$ (0.08)
Diluted	$ (0.05)	$ (0.05)	$ (0.09)	$ (0.08)
Weighted-average shares used in computing net loss per share				
Basic	118,804	110,570	116,313	110,519
Diluted	118,804	110,570	116,313	110,519
Total comprehensive loss	$ (5,482)	$ (5,481)	$ (10,420)	$ (9,077)

DURECT CORPORATION CONDENSED BALANCE SHEETS (in thousands)		
	As of June 30, 2015 (unaudited)	As of December 31, 2014[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,990	$ 2,680
Short-term investments	31,606	30,016
Accounts receivable	1,901	2,122
Inventories	3,929	3,642
Prepaid expenses and other current assets	1,170	1,034
Total current assets	44,596	39,494
Property and equipment, net	1,543	1,749
Goodwill	6,399	6,399
Long-term investments	–	1,804
Long-term restricted Investments	250	350
Other long-term assets	288	288
Total assets	$ 53,076	$ 50,084
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 654	$ 1,021
Accrued liabilities	3,770	5,051
Contract research liability	404	358
Deferred revenue, current portion	776	538
Total current liabilities	5,604	6,968
Deferred revenue, noncurrent portion	2,473	2,742
Long-term debt, net	19,862	19,824
Other long-term liabilities	2,275	2,035
Stockholders' equity	22,862	18,515
Total liabilities and stockholders' equity	$ 53,076	$ 50,084
(1) Derived from audited financial statements.		

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-corporation-announces-second-quarter-2015-financial-results-and-update-of-programs-300122640.html

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